K002711

HOLOGIC®

SEP 2 8 2000

H. SUMMARY OF SAFETY AND EFFECTIVENESS

H.1 Summary

Submitter: Denise Duchene
Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730-1401
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Date: August 30, 2000

Device: QDR® and Delphi™ Series X-ray Bone Densitometers

Classification: KGI – Densitometer, Bone – Class II

Predicate Devices: Lunar Expert-XL and DPX Bone Densitometers and Hologic, Inc. QDR and Delphi Bone Densitometers

Intended Use: For the estimation of bone mineral density (BMD) in periprosthetic bone.

Description of the Device:

The periprosthetic bone software is an added software option for the QDR and Delphi Series Bone Densitometers that can be used to estimate bone mineral density (BMD) in periprosthetic bone.

Summary of Technical Characteristics:

The periprosthetic bone software option uses the QDR and Delphi densitometer(s) method to scan bone surrounding orthopedic implants. The scan time depends upon the area to be scanned but can range from 30 seconds - 2 minutes depending on QDR and/or Delphi model used. Also the effective dose is estimated to be 1.3μSv for the QDR-4500 and Delphi Densitometer and 0.1 μSv for all other QDR Densitometer models, which is low when compared to the maximum permissible dose. The average precision (CV) in-vivo is approximately 3%, which is comparable to other marketed devices.

Conclusion:

Hologic, Inc. has determined that the additional software to add the indication for use of estimated BMD measurements in periprosthetic bone will not impact the safety or effectiveness of the product for its intended use. Software verification has shown that the proposed additional software performs as intended.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2000

Denise Duchene, RAC
Sr. Regulatory Affairs Specialist
Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730-1401

Re: K002711
QDR® and Delphi™ Series X-ray Bone Densitometers
Dated: August 30, 2000
Received: August 31, 2000
Regulatory class: II
21 CFR 892.1170/Procode: 90 KGI

Dear Ms. Duchene:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known):_____

Device Name: QDR and Delphi Series Bone Densitometers

Indications for Use:

The QDR and Delphi Series Bone Densitometers are indicated for use in the estimation of bone mineral content (BMC) and/or bone mineral density (BMD) performed at various anatomical sites, including periprosthetic bone.

The use of the QDR and Delphi Series Bone Densitometers is restricted to prescription use only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-the-Counter Use___

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K002711